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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/836,746	PATRON ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/24/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45 and 47-51* is/are pending in the application.

4a) Of the above claim(s) *1-32,37,40-43 and 47-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36,38,39,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-45 and 47-51 are pending.

Claims 1-32, 37, 40-43 and 47-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Claims 33-36, 38-39 and 44-45 are under examination.

Specification

In view of the corrections made in the specification, the objection to the specification is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 35, as amended, is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The presently claimed "predetermined" locations on a second array are not supported in the as-filed specification. The original specification does not recite how such predetermination is made. Furthermore, claim 33, step © "wherein the step of detection comprises measurement of either the expressed protein or the sample component" is not present in the original specification. MPEP 714.02 clearly states that applicants should point out where in the specification the newly added limitations appear.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 33-36, 39, and 44-45, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the Office action of 12/1/2003.

Response to Arguments

In view of the amendments to the claims and applicants' arguments the following rejections are withdrawn:

The rejections under paragraphs A, B and D.

With respect to paragraph C:

Applicants argue that Claim 38 is amended to clarify that DNA may be isolated from an expression system from which an interaction between the sample component and a protein expressed by the expression system is formed.

In response, it is not clear how a protein can express a DNA, when the DNA is one that should encode a protein when the protein is expressed in a biological composition.

The following rejections are applicable to the newly amended claims:

1. Claim 33, step (b) is unclear as to the "at least one component to be assayed" in a sample which is being inconsistent with the preamble reciting for the screening a plurality of proteins for their ability to interact with a component of a sample.

2. The terms "predetermined" and "correlated" in claim 35 are indefinite. It is not clear how such predetermination of location on a second array is accomplished, especially in the absence of positive support in the speciation. Also, it is not clear in what manner the second array is correlated with the location on the first array. Furthermore, "the first array" lack antecedent basis of support from the preceding statement.

3. Claim 44 is unclear to the detection of a chemical product as the array comprises a biological product, protein. Thus, it is not clear within the claimed context, the "chemical" product formed by the biological protein and sample interaction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 33-36, 38-39 and 44-45, as amended, are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al (U.S. 6,329,209).

Wagner discloses at col. 3, line 45 up to col. 7, line 30a method of assaying in parallel for a plurality of different proteins in a sample, which are expression products, or fragments thereof, of a cell or a population of cells in an

organism. The method comprises first contacting the sample with an array of spatially distinct patches of different protein-capture agents under conditions suitable for protein binding, wherein each of the proteins being assayed is a binding partner of the protein-capture agent of at least one patch on the array. The last step of the method involves detecting, either directly or indirectly, for the presence or amount of protein bound to each patch of the array. The array can be bound proteins, which comprise both the array of protein-capture agents and a plurality of different proteins which are expression products, or fragments thereof, of a cell or population of cells in an organism, where each of the different proteins is bound to a protein-capture agent on a separate patch of the array. "Protein-capture agent" is defined as a molecule or a multi-molecular complex, which can bind a protein to itself. Protein-capture agents preferably bind their binding partners in a substantially specific manner. The protein-capture agent will most typically be a biomolecule such as a protein or a polynucleotide. The biomolecule may optionally be a naturally occurring, recombinant, or synthetic biomolecule. Antibodies or antibody fragments are highly suitable as protein-capture agents. Antigens may also serve as protein-capture agents, since they are capable of binding antibodies. A receptor which binds a

protein ligand is another example of a possible protein-capture agent. The term "binding partner" is defined as a protein which is bound by a particular protein-capture agent, preferably in a substantially specific manner. In some cases, the protein-capture agent may be a cellular or extracellular protein and the binding partner may be the entity normally bound in vivo. The binding partner may be the protein or peptide on which the protein-capture agent was selected (through in vitro or in vivo selection) or raised (as in the case of antibodies). A binding partner may be shared by more than one protein-capture agent. For instance, a binding partner which is bound by a variety of polyclonal antibodies may bear a number of different epitopes. One protein-capture agent may also bind to a multitude of binding partners, for instance, if the binding partners share the same epitope. An "expression product" is a biomolecule, such as a protein, which is produced when a gene in an organism is expressed. An expression product may optionally comprise post-translational modifications. The entire method can be performed using 96-well assay plates. The expression vectors contain the sequences for affinity tags and the protein adaptors. PCR products are ligated into the expression vectors (under inducible promoters) and introduced into the appropriate competent Escherichia coli strain. Transformed Escherichia coli

cells are plated and individual colonies transferred into 96-array blocks. Cultures are grown, induced for expression, and cells collected by centrifugation. Cells are resuspended containing lysozyme and the membranes broken. The supernatants are transferred to 96-tube arrays. The appropriate affinity matrix is added, the protein-capture agent of interest is bound and nonspecifically bound proteins are removed by repeated washing steps using 12-96 pin suction devices and centrifugation. The proteins are eluted and transferred to a new 96-well array. The arrays of protein-capture agents may also be used to compare the protein expression patterns of two cells or populations of cells. In this method, a sample containing expression products, or fragments thereof, of a first cell or population of cells is delivered to the array of protein-capture agents under conditions suitable for protein binding. In an analogous manner, a sample containing expression products, or fragments thereof, of a second cell or population of cells to a second array, is delivered to a second array which is identical to the first array. Preferably, both arrays are then washed to remove unbound or nonspecifically bound components of the sample from the arrays. In a final step, the amounts of protein remaining bound to the patches of the first array are compared to the amounts of protein remaining bound to the corresponding

patches of the second array. If it is desired to determine the differential protein expression pattern of two cells or populations of cells, for instance, then the amount of protein bound to the patches of the first array may be subtracted from the amount of protein bound to the corresponding patches of the second array. A wide range of detection methods may be either quantitative or qualitative. The invention array can be interfaced with optical detection methods such as absorption in the visible or infrared range, chemoluminescence, and fluorescence (including lifetime, polarization, fluorescence correlation spectroscopy (FCS), and fluorescence-resonance energy transfer (FRET)). Quartz crystal microbalances and desorption processes (see for example, U.S. Pat. No. 5,719,060) provide still other alternative detection means for the array. (Note that this '060 patent also discloses time of flight spectrometry and electrospray). See the Examples starting at col. 38, line 30. Accordingly, the specific method steps of Wagner fully meet the broad claimed method steps using broad components.

In view of the amendments to the claims and applicants' arguments the 102 rejections over Weiner is withdrawn.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 1-23,37, 40-43 and 47-51 drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

9/14/05